

PATENT APPLICATION
Docket No.: 080060-0002
(Formerly 302018.3003-100)

UNITED STATES PATENT AND TRADEMARK OFFICE

First Applicant: Salomon, Daniel R.
Application No: 10/006,562 Filing Date: December 05, 2001
Group Art Unit: 1653 Examiner: Abdel A. Mohamed

For: COMPOSITION AND METHOD FOR TREATING CHRONIC
ALLOGRAFT REJECTION

<p>MAIL STOP AF Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450</p>	<p><u>CERTIFICATE OF TRANSMISSION UNDER 37 CFR 1.8</u> I hereby certify that this correspondence is being facsimile transmitted to (703) 872-9306 at the U.S. Patent and Trademark Office on the date shown below or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on <u>July 25, 2005</u> <u>Stephanie Klausner</u> (Typed or printed name of person mailing paper or fee) <u>Shlausner</u> (Signature of person mailing paper or fee)</p>
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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

This Information Disclosure Statement is submitted:

07/28/2005 MBIZUNES 00000008 071509 10006562
02 FC:1806 180.00 DA

☐ under 37 CFR 1.129(a), or
(First/Second submission after Final Rejection)

☐ under 37 CFR 1.97(b), or
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

☐ under 37 CFR 1.97(c) together with either:

☐ a Statement under 37 CFR 1.97(e), as checked below, or

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(More than 3 months after receipt of the International Search Report, but before final action or notice of allowance, whichever occurs first)

☒ under 37 CFR 1.97(d) together with:

☐ a Statement under 37 CFR 1.97(e), as checked below, and

☒ a \$180.00 fee under 37 CFR 1.17(p), or

(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

☐ under 37 CFR 1.97(i):

Applicant requests that the IDS and cited reference(s) be placed in the application
filewrapper. (Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

Enclosed herewith is form PTO-1449:

- ☒ Copies of the Supplementary Search Report in a counterpart European application BA and references BB – BS are enclosed.
- ☐ In accordance with 37 C.F.R. § 1.98 (d), copies of cited references (*list reference not enclosed*) are not enclosed as these references were entered in earlier application, U.S. Application No. [], to which the present application claims priority under 35 U.S.C. 120. The earlier application contains copies of the cited references.
- ☐ If copies of references [*list references not enclosed*] would benefit the Examiner of this case, the Examiner is invited to call the undersigned attorney and copies will be forwarded immediately.
- ☒ Listed references BH and BP were cited in the enclosed Supplementary Search Report in a counterpart European application BA. The two other references cited in the Supplementary Search Report BA are already of record, having been submitted as documents AR and AA2 with the Information Disclosure Statement mailed May 13, 2002.

Concise Explanation Requirement (non-English references):

- ☐ The "concise explanation" requirement (non-English references) for reference(s) [BB] under 37 CFR 1.98(a)(3) is satisfied by:
 - ☐ the explanation provided on the attached sheet.
 - ☐ the explanation provided in the Specification.
 - ☐ submission of the enclosed International Search Report.
 - ☐ the enclosed English language abstract.

☐ Applicant requests that the following pending applications be considered:

Examiner's
Initials

____ U.S. Patent Application No. [], Publication No. [], Publication Date [],
by [inventor(s)], filed [], Docket No.: []

____ U.S. Patent Application No. [], Publication No. [], Publication Date [],
by [inventor(s)], filed [], Docket No.: []

____ U.S. Patent Application No. [], Publication No. [], Publication Date [],
by [inventor(s)], filed [], Docket No.: []

Examiner

Date

☐ A copy of each above-cited application, including the current claims, is enclosed.

☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

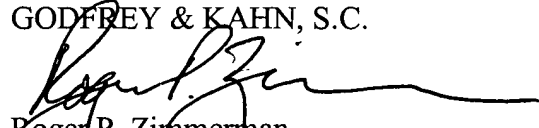
☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.

☒ Please charge Deposit Account No. 07-1509 in the amount of \$ 180.00. A copy of this Statement is enclosed.

☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account No. 07-1509.

Respectfully Submitted,

GODFREY & KAHN, S.C.


Roger P. Zimmerman
Registration No. 38,670
Date: July 25, 2005

Attorney of Record for Applicant
GODFREY & KAHN, S.C.

780 North Water Street
Milwaukee, WI 53202-3590

Telephone: 608-284-2613

Facsimile: 608-257-0609

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PTO-1449 REPRODUCED		ATTORNEY DOCKET NO. 080060-0002 (Former 302018.3003-100)		APPLICATION NO. 10/006,562			
INFORMATION DISCLOSURE CITATION IN AN APPLICATION (7/25/2005) (Use several sheets if necessary)		APPLICANT Salomon, Daniel R. & Cramer, Donald V.					
		FILING DATE December 5, 2001		GROUP ART UNIT 1653			
U.S. PATENT DOCUMENTS							
EXAM- INER INI- TIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	BA	Supplementary European Search Report Dated 08 Feb 2005, Application No. EP 02 80 4721					
	BB	Aranda JM Jr, Hill J., Cardiac transplant vasculopathy. Chest. 2000 Dec;118(6):1792-800.					
	BC	Bueno V, Pestana JO. The role of CD8+ T cells during allograft rejection. Braz J Med Biol Res. 2002 Nov;35(11):1247-58.					
	BD	Chandraker A, Azuma H, Nadeau K, Carpenter CB, Tilney NL, Hancock WW, Sayegh MH. Late blockade of T cell costimulation interrupts progression of experimental chronic allograft rejection. J Clin Invest. 1998 Jun 1;101(11):2309-18.					
	BE	Choy JC, Kerjner A, Wong BW, McManus BM, Granville DJ. Perforin mediates endothelial cell death and resultant transplant vascular disease in cardiac allografts. Am J Pathol. 2004 Jul;165(1):127-33.					
	BF	Demetris, et al., Pathophysiology of Chronic Allograft Rejection CME, March 29, 2000, http://www.medscape.com/viewprogram/336_pnt , visited 7/21/2005, p 1-71.					
	BG	Fischbein MP, Yun J, Laks H, Irie Y, Fishbein MC, Bonavida B, Ardehali A. Role of CD8+ lymphocytes in chronic rejection of transplanted hearts. J Thorac Cardiovasc Surg. 2002 Apr;123(4):803-9.					
	BH	Grieb P, Ryba M, Janczewski W, Sawicki J, Jagielski J, Andrychowski J. 2-Chloro-2'-deoxyadenosine (2-CdA) combined with cyclosporine A successfully prevents rejection of fetal brain stem allograft in rabbits. Arch Immunol Ther Exp (Warsz). 1994;42(1):43-6.					
	BI	He C, Schenk S, Zhang Q, Valujskikh A, Bayer J, Fairchild RL, Heeger PS. Effects of T cell frequency and graft size on transplant outcome in mice. J Immunol. 2004 Jan 1;172(1):240-7.					
	BJ	Hollenberg SM, Klein LW, Parrillo JE, Scherer M, Burns D, Tamburro P, Oberoi M, Johnson MR, Costanzo MR. Coronary endothelial dysfunction after heart transplantation predicts allograft vasculopathy and cardiac death. Circulation. 2001 Dec 18;104(25):3091-6.					
	BK	Kobashigawa J. What is the optimal prophylaxis for treatment of cardiac allograft vasculopathy? Curr Control Trials Cardiovasc Med. 2000;1(3):166-171.					
	BL	Knoop C, Haverich A, Fischer S. Immunosuppressive therapy after human lung transplantation. Eur Respir J. 2004 Jan;23(1):159-71.					
	BM	Koh KP, Wang Y, Yi T, Shiao SL, Lorber MI, Sessa WC, Tellides G, Pober JS. T cell-mediated vascular dysfunction of human allografts results from IFN-gamma dysregulation of NO synthase. J Clin Invest. 2004 Sep;114(6):846-56.					

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FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	BN	Kouwenhoven EA, IJzermans JN, de Bruin RW. Etiology and pathophysiology of chronic transplant dysfunction. Transpl Int. 2000;13(6):385-401.					
	BO	Mehra MR, Ventura HO, Smart FW, Stapleton DD, Collins TJ, Ramee SR, Murgo JP, White CJ. New developments in the diagnosis and management of cardiac allograft vasculopathy. Tex Heart Inst J. 1995;22(2):138-44					
	BP	Oberhuber G, Schmid T, Thaler W, Kaltenbacher A, Schirmer M, Liliemark J, Herbst P, Geisen F, Margreiter R, Konwalinka G. Evidence that 2-chlorodeoxyadenosine in combination with cyclosporine prevents rejection after allogeneic small bowel transplantation. Transplantation. 1994 Sep 27;58(6):743-5.					
	BQ	Shapiro R. Low toxicity immunosuppressive protocols in renal transplantation. Keio J Med. 2004 Mar;53(1):18-22.					
	BR	Shi C, Lee WS, He Q, Zhang D, Fletcher DL Jr, Newell JB, Haber E. Immunologic basis of transplant-associated arteriosclerosis. Proc Natl Acad Sci U S A. 1996 Apr 30;93(9):4051-6.					
	BS	Slachta CA, Jeevanandam V, Goldman B, Lin WL, Platsoucas CD. Coronary arteries from human cardiac allografts with chronic rejection contain oligoclonal T cells: persistence of identical clonally expanded TCR transcripts from the early post-transplantation period (endomyocardial biopsies) to chronic rejection (coronary arteries). J Immunol. 2000 Sep 15;165(6):3469-83.					